

Amendment

Applicant: William C. Brunnett et al.

Serial No.: 10/776,835

Filed: February 11, 2004

Docket No.: M190.147.101 / PD266.00

Title: HIGH SPEED SURGICAL CUTTING INSTRUMENT

REMARKS

This is responsive to the Final Office Action mailed February 25, 2008. In that Office Action, claims 1-4, 6-8, 12, 26, 30, 31, 33, 34, and 38 were rejected under 35 U.S.C. §102(b) as being anticipated by Etablissements FR '884, French Patent No. 1,166,884 ("FR '884"). Claims 5, 9-11, 27-29, 32, 35-37, 44-59, 65-78, 84-94, 100-110, 116-124, 130-134, and 145 were rejected under 35 U.S.C. §103(a) as being unpatentable over FR '884.

With this Response, claims 1, 4, 8, 26, 31, 44, 53, 65, 72, 84, 88, 100, 104, 116, 119, 130 and 132 have been amended. Additionally, claims 7, 34, 55, 75, 91, 107, 122 and 133 have been cancelled and claim 146 has been added. Claims 1-5, 8-33, 35-54, 56-74, 76-90, 92-106, 108-121, 123-132, 134-139, 145 and 146 remain pending in the application and are presented for reconsideration and allowance.

Subject Matter of Amendments

Each of the independent claims, namely claims 1, 26, 44, 65, 84, 100, 116 and 130 have been amended to recite, *inter alia*, an instrument having an outer tube comprising a first curved segment and a wire that, upon final assembly of the instrument, assumes a shape of the first curved segment, as recited previously in several of the dependent claims. Additionally, claims 1 and 26 have been amended to recite that the instrument is configured to allow rotation of an inner wire assembly relative to the outer tube at a speed in excess of 50,000 RPM without failure of the bearing. Several of the dependent claims have been amended to preserve clarity. Dependent claim 8 was amended to change dependency from claim 7, which was cancelled, to claim 1.

Claim 146 has been added and depends from claim 1. Claim 146 recites that the coupling chuck includes a first passageway and a second passageway. Support for new claim 146 can be found in the specification at page 13, lines 11-28. It is submitted that FR '884 does not teach or render obvious the coupling chuck recited in claim 146.

35 U.S.C. §§102, 103 Rejections

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Independent claims 1 and 26 were each rejected under 35 U.S.C. §102(b). Due to amendments of these claims, however a rejection under 35 U.S.C. §102(b) in view of FR '884 would be improper, since FR '884 clearly does not teach an instrument operating at a speed in excess of 50,000 RPM. Thus, Applicant will address the rejection of claims 1 and 26, as well as claims depending therefrom, under 35 U.S.C. §103(a).

Applicants respectfully traverse the rejections of the claims under 35 U.S.C. §103(a) and respectfully request reconsideration of the rejections in light of secondary considerations as discussed below. Secondary considerations, as delineated in MPEP § 2141, can include commercial success, long felt but unsolved needs and failure of others.

A. Commercial Success

Submitted herewith is a declaration from Mr. Scott Carpenter providing evidence of commercial success for the Visao® curved bur (see Exhibit A), which embodies features in the claims. As provided by Mr. Carpenter, revenue (see Exhibit B) and volume (see Exhibit C) for the curved bur has steadily increased since its introduction, as has the number of curved burs sold that embody features in the claims. With particular reference to cochlear implant procedures, the Visao® curved bur has established a significant market share due to its effectiveness in performing these procedures (see Exhibit D). For at least these reasons, it is apparent that the claims recite features that have established commercial success and are not obvious in view of FR '884.

B. Long Felt Need

Prior to development of the instruments of the pending application, existing surgical cutting instruments used in cutting tissue at delicate, confined surgical sites were overtly large/straight, could not operate at high cutting speeds (e.g., greater than 50,000 RPM), or both. These inherent drawbacks associated with prior cutting instruments are described in detail at page 1, line 9 – page 4, line 13. A broad goal of providing a high speed surgical cutting instrument has long since existed, but never achieved. Importantly, providing the high rotational speeds desired by surgeons, in many instances with a curved extender, requires much more than simply choosing different materials or constructions as compared to known instruments. If this

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were all that was needed, a plethora of high speed cutting instruments would be available. This is not the case. Instead, extensive inventive efforts are required to improve upon conventional designs.

In particular, prior surgical cutting instruments generally take one of two forms. Either a curved instrument capable of low speed operations only, or a more robust design capable of higher speed cutting but requiring large, inflexible components (e.g., ball bearings). Through the inventive efforts of the inventors of features recited in the claims, the long felt needs identified above have been addressed. By addressing these needs, Applicants have overcome several inherent drawbacks in the prior art. For at least these reasons, features recited in the claims are not merely obvious in view of FR '884.

C. Failure of Others

In addition, modifying FR '884 to provide high-speed, long-term operation requires more than simply experimenting with different materials. To the contrary, specific features must be conceived and reduced to practice as done by the inventors of the pending application. Pointedly, one of skill would not understand FR '884 as suggesting or making obvious the high speed surgical cutting instrument described and claimed. As set forth in the previously submitted Declaration of William C. Brunnett, the piano wire construction of FR '884 failed at the high speeds contemplated by the present application. Thus, one of skill would not consider the high speed surgical cutting instruments of the present application as being made obvious by FR '884. *Brunnett Declaration at Paragraphs 6-8*. For at least these reasons, it is apparent that others have failed at developing an instrument that is curved and operates at high speeds for surgical cutting uses. As such, the present claims are not merely an obvious design choice in view of FR '884, but represent an inventive instrument.

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CONCLUSION

In view of the above, Applicant has established that the present claims are not obvious in view of FR '884. In particular, instruments embodying features in the claims have established commercial success, addressed a long felt need and succeeded where others have failed. Thus, Applicant respectfully submits that pending claims 1-5, 7-139, 145 and 146 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-5, 7-139, 145 and 146 are respectfully requested.

Applicants hereby petition for an extension of time. If additional fees are required for the petition, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this communication should be directed to Todd R. Fronек at Telephone No. (612) 767-2522, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

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By their attorneys,

Date: 8/25/08

TAC:TRF:jms


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